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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/538,649 | 06/10/2005 | Michael Huenerbein | 3223-104 | 3729 |

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| EXAMINER |
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TOWA, RENE T

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| ART UNIT | PAPER NUMBER |
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3736

| SHORTENED STATUTORY PERIOD OF RESPONSE | NOTIFICATION DATE | DELIVERY MODE |
|--|-------------------|---------------|
| 3 MONTHS | 02/06/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/06/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/538,649

Applicant(s)

HUENERBEIN, MICHAEL

Examiner

Rene Towa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to an amendment filed November 20, 2006.

Claims 1-11 are pending. Claims 1 & 10-11 have been amended. No claim has been cancelled or added.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 5 & 9, at line 3, the phrase "in particular" renders the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Regarding claims 10-11, at line 10, the limitations "the free lying opening" lack sufficient antecedent basis; for example, there is no prior recitation of this limitation in the claim.

More in regard to claim 9, the claim provides for the use of an optical biopsy instrument for endoscopy and/or biopsy of duct systems having small diameters, but, since the claim does not set forth any steps involved in the method/process, it is unclear

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what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gatto (US Publication No. 2003/0181823) in view of Lifton (US 4,651,753).

7. In regards to claim 1, Gatto discloses an optical biopsy instrument (see figure 1), comprising

- (a) a substantially cylindrical cannula (14) inherently having a proximal end and a distal end, said cannula (14) having at least one opening (see par 0038), and
- (b) an endoscope (12) which is axially movable inside [0036] the cannula (14).

In regards to claim 2, Gatto discloses an optical biopsy instrument (Figure 1), characterized in that the at least one opening of the cannula (12) has at least in parts a cutting region (35) at its area being directed towards the distal end.

In regards to claim 3, Gatto discloses an optical biopsy instrument (see figure 1), characterized in that the cutting region (35) is formed by a ground edge 34 of the circumference of the at least one opening (see fig. 4; see par 0038 at lines 1-3).

In regards to claim 4, Gatto discloses an optical biopsy instrument (see figure 1), characterized in that the at least one opening has a substantially oval configuration.

In regards to claim 6, Gatto discloses an optical biopsy instrument (see figure 1), characterized in that an external diameter of the endoscope (12) substantially corresponds to an internal diameter of the cannula (14) or is slightly smaller than this [see paragraph 0036].

In regards to claim 7, Gatto discloses an optical biopsy instrument (see figure 1), characterized in that an external diameter of the cannula is 1.2 mm at most (see par 0036).

In regards to claim 8, Gatto discloses an optical biopsy instrument (see figure 1) characterized in that the endoscope (12) is a rigid endoscope.

In regards to claims 9-10, Gatto discloses a method for sampling tissue samples in duct systems, wherein

- (a) an optical biopsy instrument (see figure 1), comprising a substantially cylindrical cannula (14) inherently having a proximal end and a distal end, said cannula (14) having at least one opening, and an endoscope (12) which is axially movable inside the cannula (14) is introduced, under endoscopic monitoring, into the duct up to a biopsy site, [see par 0036]
- (b) the tissue sample is brought through the free lying opening into an interior of the cannula (14) (see par 0038; see par 0042).

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In regards to claim 11, Gatto discloses a method for sampling tissue samples in duct systems, wherein

- (a) an optical biopsy instrument (see figure 1), comprising a substantially cylindrical cannula (14) inherently having a proximal end and a distal end, said cannula (14) having at least one opening, and an endoscope (12) which is axially movable inside the cannula (14) is introduced, under endoscopic monitoring, into the duct, until the opening comes to lie over a biopsy site,
- (b) the tissue sample is brought through the free lying opening (38) into an interior of the cannula (14) (see par 0036, 0038, 0042).

Gatto discloses an instrument, as described above, that teaches all the limitations of the claims except Gatto does not explicitly teach a lateral opening in a side surface of the cannula or separating the tissue sample from the rest of the tissue by moving forward the endoscope across the lateral opening.

However, Lifton discloses an instrument for endoscopic multiple biopsy (see abstract) comprising a cannula 1 having a lateral opening 3 (see fig. 1); wherein the cannula 1 is closed at its distal end by a wall 7 (see fig. 1; column 3/lines 11-14); wherein the tissue sample is separated from the rest of the tissue by moving a plunger 17 forward and backward across the lateral opening 3 (see figs. 3A-F; column 3/lines 41-49).

Since Gatto teaches an opening 38 for collecting tissue samples (see par 0038), it would have been obvious to one of ordinary skill in the art at the time Applicant's

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invention was made to provide an instrument similar to that of Gatto with a lateral opening similar to that of Lifton because both openings would perform the same purpose of collecting tissue samples (see Lifton, see figures 3A-F).

It would have further been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an instrument similar to that of Gatto with a closed distal end wall similar to that of Lifton in order to provide a cavity for storing biopsy samples without removing the instrument (see Lifton, column 3/lines 24-30). Moreover, since Gatto suggests a cannula made of transparent plastic material (see par 0036 at lines 7-11), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an instrument similar to that of Gatto as modified by Lifton above with a transparent end wall as claimed since such a modification would amount to a design choice. It has previously been held that merely changing aesthetic design is not patentable--See *In re Seid*, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

More in regard to claims 9-11, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an instrument similar to that of Gatto with a method wherein the tissue sample is separated by a reciprocating plunger similar to that of Lifton in order to tear up tissue drawn into the lateral opening (see Lifton, figs. 3A-F; column 3/lines 41-49). Furthermore, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Gatto as modified by Lifton above, with a reciprocating endoscope as claimed since such a modification would amount to a design choice that

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would serve the same purpose of reciprocating a plunger to tear up tissue drawn into the lateral opening.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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